K072292

510(k) Summary

Dima Italia Srl
Via C. Vighi 29
Bologna, Italy 40133

Lewis Ward
Consultant

JAN - 7 2008

Prepared 7-13-07

L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, CO 80301
303-530-3279
303-530-4774 Fax

Device Name: Pegaso Cough

Indications for Use:

For use on patients unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube. For use in a hospital, institutional setting, or home use given adequate training. For use on adult or pediatric patients.

Device: Positive Pressure Intermittent Breathing Device

Common Name: Cough Assist Device

SE Predicate: Emerson Cough Assist, Model CA-3000
J.H. Emerson Company
K002598
868.5905

Device Description:

The Pegaso Cough Assist is a negative pressure, non-invasive ventilation system useful in clearing retained bronchopulmonary secretions. It produces a patient "cough" simulation, applying a positive pressure to the airway, then rapidly going to a negative pressure. At the end of this pressure shifting, the Pegaso Cough leaves the airway free, at zero pressure, for a pause time determined by the operator. The Peak Inspiratory Flow can be selected on three different levels: High, Medium, Low.

This "forced insufflation-exsufflation" is designated for patients with reduced coughing possibilities due to muscular dystrophy, myasthenia gravis, poliomyelitis, and respiratory muscle paralysis such as spinal cord injury. Even patients with other diseases, such as emphysema and cystic fibrosis, can be treated with the Pegaso Cough. It may be used with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube. The Pegaso Cough is indicated for use in a hospital, institutional setting, or home use given adequate training.

The Cough Assist device applies a positive pressure in the airway initially. The device shifts to a negative pressure through a facemask, mouthpiece, or an adapter to the patient's endotracheal tube or tracheostomy tube. The rapid shift produces a high expiratory flow from the lungs simulating a cough and clearing secretions. At the end of this pressure shifting, the Pegaso Cough leaves the airway free at zero or ambient pressure. A pause time between cycles is operator selected.

FDA classifies this device as a noncontinuous ventilator under 868.5905, Product Code NHJ under the Anesthesiology Review Panel. The device meets the requirements for medical equipment general requirements for basic and essential safety performance and electromagnetic compatibility.

The Pegaso Cough is comparable to the Emerson Cough Assist cleared under K002598 and have the similar indications for use.

The device is software controlled and has safety alarms for no pressure, high pressure, valve fault, low pressure, and power failure. Performance is controlled from a touch screen keyboard in manual or automatic modes.

Standards Met:

IEC 60601-1	Medical Equipment
IEC 60601-1-4	Programmable Electrical Medical Systems
EN ISO 9703-3	Anesthesia and Respiratory Care Alarm Signals
EN 60601-1-2	Electromagnetic Compatibility
EN 794-1 and -2	Lung Ventilator

Comparison Table

Feature	Emerson Cough Assist	Dima Italia Negavent DA-3 Plus Pegaso Cough
Use settings	Home, hospital/institution	Home, hospital/institution
Patient Use	Adult and pediatric	Adult and pediatric
Maximum Positive Pressure	+60 cm H_2O (44 mm Hg)	+70 cm H_2O
Maximum Negative Pressure	-60 cm H_2O (44 mm Hg)	-70 cm H_2O
Maximum Inhalation Flow	3.3 liters/second	2.9 liters/second
Positive Pressure	0 to +70 cm H_2O	+5 to +70 cm H_2O, 1 cm H_2O steps
Negative Pressure	0 to -70 cm H_2O	-5 to -70 cm H_2O, 1 cm H_2O steps
Mode of Operation	- Automatic and manual timing - Mechanical switch controlled	- Automatic and manual modes - Microprocessor controlled
Inhalation, Exhalation, and Pause Times	0 to 5 seconds	0.1 to 9.9 seconds
Blower	Two speed, High & Low, centrifugal with AC/DC brush motor	Brushless blower, High, Medium, and Low speeds
Input voltage	60 Hz	50/60 Hz
Power Supply	110/220V	110/230V
Weight	24 pounds	9.9 pounds
Humidity Operating humidity range Storage humidity range	 30-75% 10-90%	 10-90% 10-90%
Safety Class Standards	 BF type equipment EN60601-1 EN60601-1-2 EN60601-1-4	 BF IEC 60601-1 IEC 60601-1-2 IEC 60601-1-4 EMC IEC 6060101-2, FCC Part 15, Class B
CE Conformity	Risk Class IIb CE 0413	Risk Class IIb 93/42 EEC Directive CE 0476
Line Voltage Frequency Power	 110-230Vac 50/60 Hz	 110-230Vac 50/60 Hz 250W through removable cables
Fuses	T 3.0 AL 250V Unknown 110V	2x3.15 A-T for 110V 2x2A-T for 230V

Feature	Emerson Cough Assist	Dima Italia Negavent DA-3 Plus Pegaso Cough
Signaling of Alarm	- Power Failure - Others Unknown	- Power Failure - No pressure - High pressure - Valve fault - Low pressure - Fuse Failure
Contraindications	- Bullous emphysema - Pneumothorax - Pneumo-mediastinum - Barotrauma	- Bullous lung disease - Pneumothorax - Extremely low blood pressure - Pneumocephalus or pre-existing CSF leaks or head trauma - Severe cardiac rhythm disturbances - Acute facial trauma

Pegaso Cough Assist
Similarities and Differences

The Dima Italia Pegaso Cough ventilator is substantially equivalent to the Emerson Cough Assist device.

Similarities:

1. Both devices have similar Indications for Use.
2. The fundamental technology is similar. Both produce positive and negative pressures to simulate a patient's cough reflex. Both are controlled to sense pressures and develop negative and positive pressures in a controlled manner.
3. Both devices meet safety evaluations under ISO 60601 standards and ventilator standards.
4. Pressures developed for positive and negative values are comparable.
5. Pressures are developed by electronically powered blowers for both products.
6. Both units are available in 110V and 220V/230V versions.
7. Both units are intended for adult and pediatric patients in home, hospital, and institutional settings.
8. Both have comparable adjustments to produce positive and negative pressures, and rapid shifting resulting in a simulated patient cough reflex.
9. Both products simulate a cough using "mechanical insufflation-exsufflation". This is achieved in both devices by applying a positive pressure to the airway initially and rapidly shifting to a negative pressure. The change in pressure effect produces a high expiratory flow from the lungs.
10. Both devices may be used with a facemask, mouthpiece, and patient's endotracheal or tracheostomy tube.
11. Both devices operate in a manual mode or in an automatic mode.

Differences:

1. Maximum positive and negative pressures are comparable, but the Pegaso Cough has a maximum capability 16% higher than the Emerson.
2. Inhalation, exhalation, and pause times differ. Emerson controls these events to 0 to 5 seconds. The Pegaso Cough allows operator control from 0.1 to 9.9 seconds allowing a wider range as needed by patients.
3. Unit weight of the Pegaso is less than half that of the Emerson unit through use of lightweight materials.
4. The Pegaso Cough is software controlled whereas the Emerson device is controlled by electrical switches.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2008

Dima Italia SRL
C/O Mr. Lewis Ward
Consultant
L.W. Ward and Associates, Incorporated
4655 Kirkwood Court
Boulder, Colorado 80301

Re: K072292
Trade/Device Name: Pegaso Cough
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NHJ
Dated: November 30, 2007
Received: December 7, 2007

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

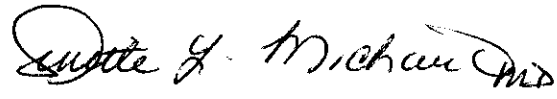
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

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Prescription Use __X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

acting B.C.

K072292